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V8

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/529,050 04/05/00 MANGEL

A PU3375USW

EXAMINER

HM22/0112

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ART UNIT

PAPER NUMBER

1614

8

DATE MAILED:

01/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/529,050

Applicant(s)

Mangel et al.

Examiner

Phyllis G. Spivack

Group Art Unit

1614



☒ Responsive to communication(s) filed on Oct 30, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 5-8 and 11-27 is/are pending in the application.

Of the above, claim(s) 19-27 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 5-8 and 11-18 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Applicants' Amendment filed October 30, 2000, Paper No. 7, is acknowledged. New claims 19-27 are presented. Accordingly, claims 5-8 and 11-27 are now under consideration.

A new title is noted.

Newly submitted claims 19-27 are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons: The search for the originally presented claims did not include the specific aspects of irritable bowel syndrome - pain, stool consistency and urgency - that are now recited respectively in independent claims 19, 22 and 25. Further search is required.

Since Applicants have received an Action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 19-27 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Following the correction of the spelling of "cilansetron", the objection to the disclosure is withdrawn.

Claims 5, 11, 14, 15 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for alosetron, does not reasonably provide enablement for any 5-HT₃ receptor antagonist in the treatment of IBS. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Due to the distinct structures among the various 5-HT₃ receptor antagonists recited in instant claims 8, 14 and 18, it would not have been

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reasonable to expect each of these diverse compounds to be effective in the treatment of IBS based solely on a particular compound's ability to antagonize 5-hydroxytryptamine under certain specific conditions.

In the last Office Action claims 5, 8, 11, 14, 15 and 18 were rejected under 35 U.S.C. 103 as being unpatentable over Kon et al., U.S. Patent No. 5,017,573. It was asserted Kon teaches the administration of indazole-3-carboxylic acid derivatives that are selective antagonists of 5-HT₃ receptors in the treatment of irritable bowel syndrome. Further, claims 5-8 and 11-18 were rejected under 35 U.S.C. 103 as being unpatentable over Bardhan et al., Gastroenterology, because Bardhan teaches the administration of alosetron for IBS.

Applicants argue the cited references do not disclose or suggest any distinction with regard to the treatment of female IBS conditions versus male IBS conditions. Applicants further urge the study results disclosed in the specification demonstrate a greater beneficial effects in female patients.

It is noted claims 15-18 make no distinction between male or female patients.

Without clear support in the present application, Applicants argue 5-HT₃ antagonists may cause constipation and thus the skilled artisan would not expect 5-HT₃ antagonists to be useful in the treatment of all forms of IBS.

Applicants' arguments have been given careful consideration but are not found persuasive. The rejections of record of the claims under 35 U.S.C. 103 are maintained for the reasons of record. It was well established at the time of the present invention that there are more women

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with irritable bowel syndrome than men at a ratio of 3:1. Kon provides motivation to administer indazole-3-carboxylic acid derivatives because IBS characterized by both diarrhea and constipation are included in the teaching. The recitation in Bardhan "altered bowel habits" includes both constipation and diarrhea.

No claim is allowed.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number (703) 308-4703.

January 11, 2001

A handwritten signature in black ink that reads "Phyllis Spivack". The signature is written in a cursive, flowing style.

**PHYLLIS SPIVACK
PRIMARY EXAMINER**